DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

February 9, 2000

Our Reference Number: 98-0464

Mr. Christopher Bentsen
Genetic Systems Corporation
6565 185th Avenue NE
Redmond, WA 98052-5039

Dear Mr. Bentsen:

This letter is in regard to your Supplement to your Product License Application for Human Immunodeficiency Virus Types 1 and 2 (Synthetic Peptide), submitted under section 351 of the Public Health Service Act, to modify the intended use of the Genetic Systems HIV-1/HIV-2 Peptide EIA to include the testing of cadaveric serum samples.

The Center for Biologics Evaluation and Research has completed the review of this Supplement, and based upon the documentation submitted in support of this request, the Supplement has been found acceptable.

This information will be placed on file with your Product License Application for Human Immunodeficiency Virus Types 1 and 2 (Synthetic Peptide).

Sincerely yours,

for Jay S. Epstein, M.D.
Director
Office of Blood Research and Review
Center for Biologics Evaluation
and Research